PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Optiray 350 - 50 ml Solution for Injection

Optiray 350 - 75 ml Solution for Injection

Optiray 350 - 100 ml Solution for Injection

Optiray 350 - 125 ml Solution for Injection

Optiray 350 Solution for Injection

Optiray 320 - 50 ml Solution for Injection

Optiray 320 - 100 ml Solution for Injection

Optiray 300 - 30 ml Solution for Injection

Optiray 300 - 50 ml Solution for Injection

Optiray 300 - 100 ml Solution for Injection

Optiray 300 - 125 ml Solution for Injection

Ioversol

Sugar free

Read all of this leaflet carefully before you are given Optiray.

- Keep this leaflet. You may need to read it again.
- If you have any further questions please ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Optiray is and what it is used for

Optiray is used for several types of X-ray procedures including:

- **imaging of vessels**, both arteries and veins
- **kidneys**
- **CT scans**

Optiray is an X-ray contrast medium containing iodine. The iodine blocks the X-rays, allowing vessels and the inner organs supplied with blood to be seen.

2. What you need to know before you use Optiray

Optiray should not be administered to you

- if you are allergic to contrast media substances containing iodine or to any of the other ingredients of Optiray (listed in section 6).
- if you have an overactive thyroid gland (hyperthyroidism).

Warnings and precautions

Tell your doctor or healthcare professional before being given Optiray if you have

- asthma or previously had allergic reactions such as nausea, vomiting, low blood pressure, skin symptoms
- heart failure, high blood pressure (hypertension), circulation disorders or had a stroke, and if you are very elderly
- diabetes
- kidney or liver disease

- brain disorders
- problems with bone marrow, such as certain blood cancers known as paraproteinaemia, multiple myeloma
- certain red blood cell abnormalities, known as sickle cell anaemia.
- a tumour of the adrenal gland, which affects your blood pressure known as phaeochromocytoma
- increased homocysteine amino acid level, due to abnormal metabolism
- recent gall bladder investigation with contrast media
- a planned thyroid gland investigation using a substance containing iodine

  This should be postponed as Optiray may influence results for up to 16 days.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (Lyell's syndrome or TEN) and acute exanthematous pustulosis (AGEP), which can be life-threatening, have been reported with the use of Optiray.

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Tell your doctor straight away if you notice any of the symptoms related to this condition described in section 4.

Children younger than 18 years

Optiray 300 is used for imaging of vessels or kidneys in this age group.

With paediatric patients younger than 3 years, including newborns whose mothers have received a iodinated contrast medium during pregnancy, controls of thyroid hormones known as TSH and T4 are recommended. These checks take place 7-10 days and 1 month after administration of Optiray.

Other medicines and Optiray

Always tell your doctor, X-ray specialist or health care provider, if you are taking or have recently taken any other medicines (this includes complementary or traditional medicines.)

The following **medicines** can **influence or be influenced by Optiray**

- **metformin:** used for treatment of diabetes. Your doctor will measure your kidney function before and after having X-ray contrast media. As metformin may accumulate in the body and lead to a serious metabolic disorder, it should be stopped at the time of the investigation. It should not be re-started for at least 48 hours after the investigation, and only when your kidney function has returned to its previous level.
- **Interleukin:** medicines used in certain types of tumours - the rate of side effects to Optiray may be increased;
- **certain medicines to increase blood pressure** (vasopressors) due to narrowing of blood vessels. To prevent any risk of nervous disorders, Optiray should never be used while using these medicines.
- **general anaesthetics**

  A higher frequency of side effects has been reported.
- **diuretics:** medicines that increase urine production and lower blood pressure

  In case of dehydration caused by the use of diuretics, the use of iodinated contrast media may increase the risk of acute kidney failure.

Optiray with food and drink

It may be necessary to restrict your food and drink prior to the examination, so please ask for advice. However, if you have kidney disease, water should not be restricted because dehydration (lack of water in the body tissue) may further decrease the kidney function.

Pregnancy and Breastfeeding

Optiray should not be used during pregnancy or lactation.

Pregnancy: If you are pregnant or there is any possibility that you may be pregnant or if you are breastfeeding your baby, please consult your doctor or X-ray specialist or other health care provider for advice before being given Opitray. The risk to the unborn baby with use of Optiray in pregnancy, cannot be excluded. However, any X-ray investigations during pregnancy may have a risk for the unborn baby.

Breastfeeding: It is not known whether Optiray is excreted in human breast milk. However, approximately 1 % of iodine-containing X-ray contrast media similar to Optiray is excreted into breast milk. Although it has not been established that this would affect your baby, you should rather discontinue breastfeeding your baby for one day after the injection. Discuss this with your doctor or X-ray specialist.

Driving and using machines

Driving or operating machines **is not advisable for up to 1 hour after** injection.

In addition, symptoms such as dizziness, drowsiness, fatigue and visual disturbances have been reported. If this affects you, do not attempt any activities which require concentration and the ability to react appropriately.

Optiray contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 100 ml, that is to say essentially "sodium-free".

3. How to use Optiray

Optiray investigations will **only** be performed **by a doctor or X-ray specialist**, who will also decide the dose.

Optiray is injected into a blood vessel and distributed throughout the body by the blood stream. It will be warmed to body temperature before use, then injected once or more during the X-ray procedure.

The dose depends on the specific procedure you are having and other factors such as your general state of health and age. The lowest dose possible will be used to produce adequate X-ray images.

If more Optiray is given than it should

Overdoses are potentially dangerous and may affect the breathing (respiratory), heart and circulation system.

Inform your doctor or X-ray specialist immediately if you notice any of these symptoms after receiving Optiray.

4. Possible side effects

Optiray can have side effects.

Not all side effects reported for Optiray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given this medicine, please consult your doctor or X-ray specialist for advice.

Side effects associated with Optiray are generally independent of the dose given. In the majority of cases they are mild or moderate and very rarely serious or life-threatening.

Contact a doctor immediately if you develop any of the following **signs of serious side effects:**

- heart attack or an inability to breathe
- severe chest pain, which could indicate heart vessel spasms or blood clots

- stroke, blue lips, fainting
- loss of memory
- speech disorders
- sudden movements
- temporary blindness
- acute kidney failure
- skin rash, redness or blisters, which may develop into life-threatening skin reactions including extensive peeling of the skin (toxic epidermal necrolysis), or a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS)
- signs of allergic reactions, such as
    - allergic shock
    - tightened airways
    - swelling of the voice box, throat, tongue
    - breathing difficulties
    - cough, sneezing
    - reddening and/or swelling of the face and eyes
    - itching, rash and hives

Side effects can occur with the following frequencies:

very common, occurs in more than 1 of 10 users

- feeling hot, pain

common, occurs in 1 to 10 per 100 users

- pain
- nausea

uncommon, occurs in 1 to 10 per 1,000 users

- hives
- skin redness, itching
- dizziness
- headache
- taste disturbance
- abnormal sensation, such as pricking, tingling
- vomiting
- sneezing
- high blood pressure

rare, occurs in 1 to 10 per 10,000 users

- fainting
- vertigo
- blurred vision
- racing pulse
- low blood pressure
- flushing
- larynx spasms
- swelling and narrowing of airways, including throat tightness, wheezing
- difficult breathing
- inflammation inside the nose which causes sneezing and blocked nose
- cough, throat irritation
- dry mouth
- rash
- urgent urination

- swelling of the face including eyes
- chills
- uncontrollable shaking
- feeling cold

very rare, occurs in fewer than 1 per 10,000 users

- severe allergic reaction
- confusion, anxiety, restlessness
- loss of consciousness, numbness
- paralysis
- drowsiness
- stupor
- speech disorders
- language disorders
- reduced sense of touch or sensation
- allergic eye inflammation causing red, watery and itchy eyes
- ringing or buzzing in the ears
- irregular heartbeats, slow pulse
- chest pain
- heart activity changes measured using ECG
- disease which disturbs blood flow through the brain
- vein inflammation, blood vessel dilation
- fluid accumulation in the lung
- sore throat
- low oxygen in the blood
- abdominal pain

- salivary gland inflammation, swelling of the tongue
- difficulty in swallowing, increased salivation
- acute kidney failure or abnormal kidney function
- urinary incontinence, blood in urine, low urination
- mostly painful severe swelling of deep skin layers, mainly in the face
- increased sweating
- muscle spasm
- tissue swelling caused by excess fluid
- injection site reactions including pain, reddening, bleeding or degeneration of cells, feeling unwell or abnormal, tiredness, sluggishness

not known: frequency cannot be estimated from the available data

- severe allergic shock reaction
- temporarily underactive thyroid
- fits
- short term brain disorders (encephalopathy) which can cause confusion, hallucination, visual disturbance, blindness, seizures loss of coordination, loss of movement in one side of the body, problems with speech and loss of consciousness
- movement disorder
- loss of memory
- temporary blindness
- heart arrest, life-threatening irregular heartbeat
- extra heartbeat
- heart artery cramps, pounding of the heart
- blue skin colouration due to low oxygen in the blood
- shock

- blood clot or spasm in a blood vessel
- paleness
- inability to breathe, asthma, tightened airways
- reduced ability to produce voice sounds using the vocal organs
- diarrhoea
- severe reaction affecting the skin, blood and internal organs (drug reaction with eosinophilia and systemic symptoms also known as DRESS or drug hypersensitivity syndrome)
- red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (Acute Generalized Exanthematous Pustulosis)
- red pimples (macular or papular eruptions)
- life-threatening reaction with flu-like symptoms and painful rash / blistering affecting the skin, mouth, eyes and genitals (Steven-Johnson Syndrome / Toxic Epidermal Necrolysis)
- absent or painful/difficult urination
- underactive thyroid in newborns
- fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or X-ray specialist.

Reporting of side effects

If you get any **side effects, talk to your doctor or X-ray specialist**.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form” found online under SAHPRA publications:

SAHPRA: https://www.sahpra.org.za/Publications/Index/8.

Guerbet South Africa (Pty) Ltd: pharmacovigilance.za@guerbet.com

By reporting side effects you can help provide more information on the safety of Optiray.

5. How to store Optiray

Store all medicines out of reach and sight of children.

Keep the container in the outer carton in order to protect from light. Protect from X-rays. Store at or below 25 °C. Optiray may be stored for one month at 37 °C in a contrast media warmer with circulating air.

Do not use the solution if you notice discolouration or particulate matter.

Do not use OPTIRAY after the expiry date stated on the label. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Optiray contains

The active substance of **Optiray 350** is ioversol. One millilitre contains 741,0 mg ioversol which is equal to 350 mg of organically bound iodine.

The active substance of **Optiray 320** is ioversol. One millilitre contains 678,0 mg ioversol which is equal to 320 mg of organically bound iodine.

The active substance of **Optiray 300** is ioversol. One millilitre contains 636,0 mg ioversol which is equal to 300 mg of organically bound iodine.

The other ingredients are trometamol, trometamol hydrochloride (buffer), sodium calcium edetate (stabiliser) and water for injections.

Sodium hydroxide and/or hydrochloric acid may be used for adjustment pH of 6,0 to 7,4.

What Optiray looks like and contents of the pack

Optiray formulations are sterile, clear, colourless to pale yellow solution containing no solids.

Optiray is packaged in type 1, colourless glass vials, fitted with 20 mm or 32 mm bromobutyl rubber closures and aluminium cap seals.

Optiray 300: 30 ml (box of 10)

50 ml (box of 10 and 25)

100 ml (box of 10 and 12)

Optiray 320: 50 ml (box of 10 and 25)

100 ml (box of 10 and 12)

Optiray 350: 50 ml (box of 10 and 25)

100 ml and 200 ml (box of 10 and 12)

500 ml (box of 5, 6 and 10)

Optiray is also supplied in prefilled hand-held syringes and power-injector syringes made of polypropylene. Blue syringe tip cap and piston are made of natural rubber.

Optiray 300, 320 and 350: 50 ml (box of 10) Prefilled hand-held syringes

75 ml, 100 ml (box of 10) Prefilled power-injector syringes

Optiray 300 and 350: 125 ml (box of 10) Prefilled power-injector syringes

Not all pack sizes and box sizes may be marketed.

Holder of Certificate of Registration

Guerbet South Africa (Pty) Ltd

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90 Bekker Road, Vorna Valley

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This leaflet was last revised in

31 October 2023

Registration Numbers

Optiray 350 – 50 ml: Z/28/420

Optiray 350 – 75 ml: A40/28/0246

Optiray 350 – 100 ml: Z/28/422

Optiray 350 – 125 ml: 30/28/0282

Optiray 350: 34/28/0101

Optiray 320 – 50 ml: Z/28/412

Optiray 320 – 100 ml: Z/28/421

Optiray 300 – 30 ml: Z/28/414

Optiray 300 – 50 ml: Z/28/418

Optiray 300 - 100 ml: Z/28/417

Optiray 300 – 125 ml: 30/28/0281

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

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Tel : 0800 110 200

Botswana: Schedule 2

Optiray 300: BOT 0700947; Optiray 350: BOT 0700948

Namibia: Schedule 2

Optiray 300-30 ml 19/28/0001; Optiray 300-50 ml 19/28/0002;

Optiray 300-100 ml 19/28/0004; Optiray 300-125 ml 19/28/0005;

Optiray 350-50 ml 19/25/0007; Optiray 350-75 ml 19/28/0008;

Optiray 350-100 ml 19/28/0009; Optiray 350-125 ml 19/28/0010;

Optiray 350 19/28/0011